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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,113	01/19/2001	Wesley B. Bruce	1166	1157

27310 7590 12/03/2003

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,113	BRUCE ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 17 September 2003.
2. New claim 24 has been added. Claims 1-10 and 24 are pending, and are examined in the instant action. Claims 11-23 and the various SEQ ID NOs other than SEQ ID NO: 2 have been withdrawn.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

6. Applicant has amended the specification as requested. Therefore the previous objection is overcome.

Claim Rejections - 35 USC § 112-1 - Written Description

7. Claims 1-10 and 24 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

8. Applicant traverses, stating primarily the Written Description Guidelines cited support a finding that the written description requirement has been met. Applicant's traversal has been considered and is unpersuasive. Whether the product by process claim or not, the invention must be described by physical and structural information. The claimed invention is adequately described if the written description adequately links or associates a particular structure, material or acts to the function recited limitation; MPEP 2163-3(a). In addition, applicant has not correlated structural and physical information with the claimed invention. Applicant refers to a sequence comprising "at least 7 contiguous nucleotides of SEQ ID NO: 2," where function is retained. But Applicant has not indicated this motif in the claimed invention.

9. Applicant traverses, stating primarily (Response, p. 16) citing the Written Description Guidelines with respect to claims 5-10. This citation says, among other things, that "disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the Applicant was in possession of the claimed species is sufficient".

Applicant's traversal has been considered and is unpersuasive. The process steps do *not impart distinguishable* information to the claimed invention.

Claim Rejections - 35 USC § 112-Enablement

10. Claims 1-10 and 24 remain rejected under 35 U.S.C. 112, first paragraph, Enablement, for reasons of record. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Applicant traverses, stating primarily (Response, p.18) that it would not be undue experimentation to test a promoter in a species. Applicant further asserts that the specification provides that a characteristic motif was present among a class of selected DNA sequence, giving reference to the sequence and where it is in the specification.

Applicant's traversal has been considered and is unpersuasive. The Examiner maintains that it would require undue experimentation to identify operable embodiments, for the reasons set forth in the previous Office Action. In addition, Applicant's arguments are not commensurate in scope with the claims. While the claims are read in light of the specification, limitations from the specification cannot be read into the claims. The claims do not currently require a specific 7-contiguous nucleotide sequence.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-10 and 24 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-19 of U. S. Patent No. 6,140,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claims of patent 6,140,080 renders the genus claims of the instant application obvious. The claimed promoter made by the method of providing a mix of oligonucleotides, contacting with nuclear proteins, isolating complexes and then the complexed oligonucleotide, amplifying the oligonucleotide by PCR, isolating oligonucleotides re electrophoretic mobility, putting the oligonucleotide with a promoter and assaying expression (steps a-l of claim 1) would have been obvious in view of the method of proving a oligonucleotide library, providing nuclear protein extracts, contacting the oligonucleotides with the nuclear protein extract, isolating separated complexed oligonucleotides, ligation of the oligonucleotide to a promoter of an expression cassette (Examples 1 & 2, columns 12-13, US 6,140,080). In addition, the specific method of making would not impart characteristics on the claimed product that would patentably distinguish the product.

Remarks

13. No claim is allowed.

14. SEQ ID NO: 2 is free of the prior art, however a 16-mer comprising a 7-mer identical to SEQ ID NO: 2 is known in the art. See Havelund, et al, US 5, 750,497, issued 12 May 1998.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-

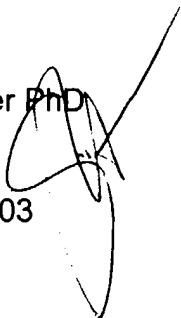
Art Unit: 1638

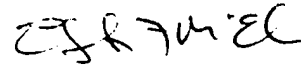
7023. The examiner can normally be reached on 8:30 - 5:00. *Note that Examiner's phone number will change to 571-272-0796 as of 6 January 2004.*

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner
Art Unit 1638
November 28, 2003




ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1000